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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/030,482	02/25/98	SNUTCH T	NMED.P-001

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EXAMINER	
BASI,N	
ART UNIT	**PAPER NUMBER**
1646	9

DATE MAILED: 05/08/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/030,482	Snutch et al
Examiner	**Group Art Unit**
Nirmal. S. Basi	1646

☒ Responsive to communication(s) filed on *Jul 19, 1999* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-15* is/are pending in the application.

Of the above, claim(s) *12 and 15* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-11, 13, and 14* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-15* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☒ The drawing(s) filed on *Feb 25, 2000* is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Response to Restriction requirement filed 7/19/99 has been entered.

Corrected Filing Receipt

2. The processing of requests for corrected filing receipts delays the issue process and because such corrected filing receipts are not needed in order to have the correct information printed on the patent. A corrected filing receipt is not necessary for correct printing because the inventors' names, the title of the invention and any priority information are separately captured by the data capture contractor from documents within the application file wrapper and not from PALM data (which is used to generate the filing receipt. The inventors and the spelling of their names are taken from the originally filed executed oath or declaration or any later papers correcting the information thereon. The title of the invention is taken from the application papers and any amendments. Foreign priority information is also taken from the oath of declaration. In view of this and the fact that filing receipt are now generated earlier in the application process (see *Changes In Practice In Supplying Certified Copies And Filing Receipts*, 1199 O. G. 38) June 10, 1997), the PTO is changing its practice with respect to requests for corrected filing receipts. The new practice is that corrected filing receipts will **not** be mailed after the date of mailing of a Notice of Allowance and Issue Fee Due unless special circumstances exists which compel such action.

Election/Restriction

3. Applicant's election of Group II Claims 1-11 and 13-14 in Paper No. 6 (7/19/99), is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 12 and 15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

4. The disclosure is objected to because of the following informalities:

The drawings objected to because each Figure must described separately in the Brief Description of the Drawings. Figure 1 is contained on two separate sheets. Figure 1 must be labeled as Figure 1A and Figure 1B and described in the Brief Description of the Drawings as Figures 1A-1B or the equivalent, as required by 37 C.F.R. § 1.84 (u)(1).

On page 13, lines 23-25, applicant suggests a translated sequence is represented by SEQ ID NO:18, said sequence represent polynucleotide and not polypeptide.

Appropriate correction is required.

5. ***Sequence Rules Compliance***

This application fails to comply with the sequence rules, 37 CFR 1.821-1.825. Nucleotide and polypeptide sequences must be identified with the corresponding SEQ ID NO. Title 37, Code of Federal Regulations, Section 1.821 states "reference must be made to the sequence by

use of the assigned identifier", the identifier being SEQ ID NO. Sequences in Figures 1 must be identified by their corresponding SEQ ID NO:.

Claim Rejection, 35 U.S.C. 112, second paragraph

6. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2 and 11 are indefinite because "non-stringent conditions" are not specified completely. The metes and bounds of the group of sequences that would meet the limitations of the claim depend upon the precise conditions under which hybridizations were performed including wash conditions. Since the hybridization and wash conditions dictate which DNA sequences remain specifically bound to the DNA encoding the polypeptide of SEQ ID NO:18 or 19 the metes and bounds of the claims cannot be determined without the disclosure of said conditions.

Claim 3 is indefinite because the name neuronal calcium channel has not been defined in the claims and specification so as to allow the metes and bounds of the claims to be determined. The name neuronal calcium channel does not sufficiently serve to characterize said polypeptide. For example does neuronal calcium channel mean a calcium cannel that is only found in neurons and no other place. Further what are the characteristics of the DNA that classify it as a neuronal calcium channel.

Claims 1, 2 and 11 are indefinite because SEQ ID NOs: 18 and 19 are nucleotide sequences and not amino acid sequences therefore it is not clear what sequences the Applicant is referring to

when stating, " amino acids set forth in SEQ ID NO:19" and " amino acids set forth in SEQ ID NO:18". It is suggested that the Applicant review accuracy of all sequences identifiers referred to in the claims and specification. Further, claim 2 is objected to because it is not clear that claim 2 further limits claim 1. Also claims 1 and 2 are indefinite because the claim recites "sequences of nucleotides that hybridize". The sequences can be mere characters on a page and can not hybridize to a DNA. It is suggested that the claim be amended to include language such as, "polynucleotide the hybridizes".

Claim 10 is indefinite because the name α-$_{II}$ subunit has not been defined in the claims and specification so as to allow the metes and bounds of the claims to be determined. The application has disclosed a partial sequences for the polynucleotide represented by SEQ ID NOs:18 and 19. The name α-$_{II}$ subunit encompasses the complete sequence of the protein and therefore does not sufficiently serve to characterize said protein. Without knowledge of the structure and function of the claimed subunit the metes and bounds of the claim cannot be determined.

Claims 3-7 are indefinite for depending on a base claim or intermediate claim and fail to resolve the issues raised above.

Claim Rejections - 35 USC § 101 and 35 USC § 112, 1st paragraph

The following is a quotation of 35 U.S.C. 101:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-11 and 13-14 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

A "specific utility" is a utility that is specific to the subject matter claimed, as opposed to a "general utility" that would be applicable to the broad class of the invention. A "substantial utility" is a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. A "well established utility" is a utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. A "well established utility" must also be specific and substantial as well as credible.

Based on the record, there is not a "well established utility" for the claimed invention.

Applicant has asserted utilities for the specifically claimed invention of claims 1-11 and 13-14. For example, the specification at page 6 asserts that, "the present invention provides partial sequences

for novel mammalian (human and rat sequences identified) calcium channel subunit", and knowledge of the polypeptides encoded by the claimed invention "permits the localization and recovery of the complete sequence from human cells, and the development of cell lines which express the novel channel proteins of the invention. These cells may be used for identifying compounds capable of acting as agonists or antagonists to the calcium channels". Further stated on page 9, "since defects in the novel calcium channel subunits may be associated with a human genetic disease including, but not limited to; epilepsy, migraine, ataxia, hypertension, arrhythmia, angina, depression, small lung carcinoma. Lambert-Eaton syndrome, characterization of such associations and ultimately diagnosis of associated diseases can be carried out with probes which bind to the wild-type or defective forms of the novel calcium channels".

The utilities asserted by Applicant are specific. However, the asserted utilities are not substantial. Neither the specification nor the art of record disclose any disease states treatable by the claimed polynucleotides or polypeptides encoded by them. Similarly, neither the specification nor the art of record disclose any instances where blocking any effects of the claimed polynucleotides or polypeptides encoded by them reduces the effect of a disease state. Thus the corresponding asserted utilities are essentially methods of treating unspecified, undisclosed diseases or conditions, which does not define a "real world" context of use. Treating an unspecified, undisclosed disease or condition would require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use especially when the complete sequence of the claimed invention is not known. Since neither the specification nor the art of record disclose any activities or properties that would

constitute a "real world" context of use for the claimed polynucleotides or the polypeptides encoded by them, further experimentation is necessary to attribute a utility to the claimed polynucleotides and encoded polypeptides. See Brenner v. Manson, 383 U.S. 519, 535–36, 148 USPQ 689, 696 (1966) (noting that "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing", and stated, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.").

8. Claims 1-11 and 13-14 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

9 Further claims 1-3, 11 and dependent claims 3-10 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Examiner has assumed claims 1-2 are directed to DNA fragments comprising SEQ ID NOs:18 and 19 and polynucleotides that hybridize to said fragments because the claims as written refer to SEQ ID NOs 18 and 19 as polypeptides, whereas they are polynucleotides. Claim 3 is directed to the polynucleotide of claim 1, where said polynucleotide is a human neuronal calcium channel. Claims 4 and 5 are directed to expression vector containing the DNA of claims 1 or 2, claims 6, 7,

8 and 9 directed to host cell containing said expression vector, and claims 10 and 11 directed to a process of expression the protein from the DNA of claim 1 or 2. The specification, on page 9, lines 14-16, discloses instant application contains partial polynucleotide sequences of a calcium channel subunit and the applicant indicates, "These subunits are believed to represent two new types of α_1 subunits of human voltage-dependent calcium channels which have been designated as type α_{1I} and type α_{1H}", and further states, "The novel α_1 subunits of the invention were identified by screening the *C. Elegans* genomic DNA sequence data base for sequence homologous to previously identified mammalian calcium channel α_1 subunits. The specification contains no disclosure of an actual molecule isolated by applicant, full length or otherwise. Further, the specification nor prior art discloses that the DNA claimed encodes a functional protein, nor what that function is or how to assay for such.

The hybridization conditions of claims 1, 2 and 11 are indefinite, as stated in the claim rejection under 35 U.S.C. 112 , second paragraph. The hybridization conditions recited in the claims do not constitute a meaningful structural limitation and the claim recite no functional language. The instant fact pattern closely resembles that in Ex parte Maizel, 27 USPQ2d 1662 (BPAI 1992). In Ex parte Maizel, the claimed invention was directed to compounds which were defined in terms of function rather than sequence (i.e., "biologically functional equivalents"). The only disclosed compound in both the instant case and in Ex parte Maizel is the, naturally occurring compound, polynucleotide represented by SEQ ID NOs: 18 and 19, in instant application. The Board found that there was no reasonable correlation between the scope of exclusive right desired by Appellant and

the scope of enablement set forth in the patent application. Even though Appellant in Ex parte Maizel urged that the biologically functional equivalents consisted of proteins having amino acid substitutions wherein the substituted amino acids had similar hydrophobicity and charge characteristics such that the substitutions were "conservative" and did not modify the basic functional equivalents of the protein, the Board found that the specification did not support such a definition, and that the claims encompassed an unduly broad number of compounds. Such is the instant situation. Clearly, a disclosed partial polynucleotide sequence does not support claims to nucleic acid hybridizing to same, given the lack of guidance regarding what sequences would hybridize specifically to SEQ ID NOs: 18-19, and not other, related sequences. Likewise the DNA fragment of claim 3, expression vectors of claims 4 and 5, cell (claims 7-8) comprising the vectors of claims 4 and 5 and process for producing protein using said vector are not enabled for these reasons given above.

Claim Rejection, 35 U.S.C. 112, first paragraph

10. Claims 1-11 and 13-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Examiner has assumed claims 1-2 are directed to DNA fragments comprising SEQ ID NOs:18 and 19 and polynucleotides that hybridize to said fragments because the claims as written refer to

SEQ ID NOs 18 and 19 as polypeptides, whereas they are polynucleotides. Claim 3 is directed to the polynucleotide of claim 1, where said polynucleotide is a human neuronal calcium channel. Claims 13 and 14 are directed to DNA fragments comprising SEQ ID NO:17 or SEQ ID NO:19. Claims 4 and 5 are directed to expression vector containing the DNA of claims 1 or 2, claims 6, 7, 8 and 9 directed to host cell containing said expression vector, and claims 10 and 11 directed to a process of expression the protein from the DNA of claim 1 or 2. The specification, on page 9, lines 14-16, discloses instant application contains partial polynucleotide sequences of a calcium channel subunit and the applicant indicates, "These subunits are believed to represent two new types of α_1 subunits of human voltage-dependent calcium channels which have been designated as type α_{1I} and type α_{1H}", and further states, "The novel α_1 subunits of the invention were identified by screening the *C. Elegans* genomic DNA sequence data base for sequence homologous to previously identified mammalian calcium channel α_1 subunits. The specification contains no disclosure of an actual molecule isolated by applicant, full length or otherwise. Further, the specification nor prior art discloses that the DNA claimed encodes a functional protein, nor what that function is.

Claims 1-3 and 13-14 as written read on genomic DNA, claims 4 and 5 read on expression vector containing said DNA, claims 6, 7, 8 and 9 read on host cell containing said expression vector, and claims 10 and 11 read on process of expression the protein from the genomic DNA. It does not appear that Applicants were in possession of such a genomic DNA, said expression vector or said cell containing said genomic DNA at the time the invention was made. *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111 makes clear that the written description provision of 35 U.S.C. §112 is severable from

its enablement provision (see page 1115). The specification gives no sequence of any gene, where gene means genomic DNA encoding a protein. There is no guidance provided to allow the skilled artisan to predict the structure of a gene corresponding to the cDNA, particularly in light of the lack of an example or the structure of even a single gene. Even though cDNA which may be part of a genomic DNA segment is disclosed, what is present besides the cDNA, is not know. Due to their nature, genes are very complex structures which are made of coding and non-coding regions (exons and introns, respectively). The sequences disclosed do not contain any intron sequence(s) since the sequence is of cDNA , which is made of only exon sequence. Further the polynucleotides of the present invention encode partial sequences of the "believed" novel calcium channel. There is no disclosure of what the intron or additional exon sequences of the genomic DNA. The skilled artisan could not predict either the number or position of introns or additional exons in the claimed genomic polynucleotide or their nucleic acid sequences. Even assuming high skill of the artisan, one could not predict if there are additional coding regions in the genomic DNA besides what is shown in SEQ ID NO:17-19. Further vectors containing genomic DNA nor cells containing said vectors are disclosed. Further methods of using said genomic DNA are rejected for the reasons given above.

No claim is allowed.

Applicant must pay the filing/claim fees due, see attached NOTICE OF FILING/CLAIM FEE(S) DUE.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Thursday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi
Art Unit 1646
May 2, 2000

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER